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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,004	11/14/2003	Stuart A. Kushon	8971-035-27	7816

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EXAMINER
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VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/712,004	KUSHON ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on May 26, 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-24, 27-31 and 33-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 18-24, 27-30 and 33-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16, 18-24, 27-31 and 33-61 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on November 14, 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION*****Election/Restrictions***

Amended claims 16, 18-24, 27-30, 40-42, 52, 55-57 and 58-61 are directed to an invention that is independent and distinct from the invention originally presented. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 and 54, drawn to methods of making a sensor, classified in class 548/304.1, for example.
- II. Claims 16, 18-24, 27-30, 40-42<sup>1</sup>, 52, 55-57 and 58-61, drawn to a sensor and sensing system comprising a solid support, classified in class 436/7.92, for example.
- III. Claim 31, drawn to a sensor comprising a fluorescent protein, classified in class 435/69.7, for example.
- IV. Claims 33-39, 43-48 and 53, drawn to methods for detecting analyte, classified in class 435/7.5, for example.
- V. Claim 49, drawn to a sensor, classified in class 435/DIG. 4, for example.
- VI. Claims 50-51, drawn to methods for detecting analyte, classified in class 435/5, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, IV and VI are independent and patentably distinct from each other. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions modes of operations. For example, Invention I requires the step of combining a polymer and a protein, while Invention IV requires the step of combining a sample and a bioconjugate, while Invention VI requires the step of incubating a sample and a bacterial spore or virus.

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Inventions I and (II, III or V) are related as process of making and products made, respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make a materially different product, such as a drug delivery system.

Inventions (II, III or V) and (IV or VI) are related as products and processes of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in a materially different process, such as a drug delivery system.

Inventions II, III and V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions have different designs because Invention II requires a solid support, while Invention III requires a fluorescent protein, while Invention V requires a spore or virus. The inventions have different modes of operation because Invention II appears to require tether-binding, while Invention III appears to require disruption of a biotinylated fluorescent polymer:biotinylated fluorescent protein:biotin-bind protein complex, while Invention V appears to require binding to coat proteins. The inventions have different effects because Invention II appears to effectuate biotin binding to a solid support, while Invention III appears to effectuate "biotin binding site" recognition, while Invention V effectuates "target biological species" recognition.

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<sup>1</sup> Independent claim 40 references cancelled claim 25. For purposes of the instant requirement for Election/Restriction, Examiner assumes Applicants intend for claim 40 to reference claim 16.

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In Applicants' reply, filed October 11, 2005, Applicants elected with traverse to prosecute Invention II. However, Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement. Therefore, in the Office Action, dated January 26, 2006, the restriction requirement was made FINAL.

The restriction requirement remains FINAL.

Applicants have received an action on the merits for the originally presented invention corresponding to Invention III, *supra*. Applicants constructively elect Invention III by original presentation for prosecution on the merits.

Accordingly, claims 1-16, 18-24, 27-30, 33-61 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

Currently, claim 31 is under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Response to Amendment***

Applicants' amendment filed May 26, 2006, is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. Pursuant to Section 132(a) of 35 U.S.C., no amendment shall introduce new matter into the disclosure of the invention. Specifically, Applicants' amendment to the chemical structure on p. 33 (after line 10) deleting reference to R group species constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Specification***

The disclosure is objected to because of the following informalities:

On p. 4, line 20, the object "the solution" lacks antecedent basis.

On p. 5, line 6, the object "the solution" lacks antecedent basis.

On p. 7, lines 3-4, the phrase "a fluorescent polymer complex disposed on a solid support as set forth above" lacks antecedent basis. The identity of one or more locations referenced by the term "above" is not clear.

On p. 8, line 1, the object "the fluorescer" lacks antecedent basis.

On p. 8, line 15, the phrases "a fluorescent polymer complex as set forth above" and "a sensor comprising a fluorescent polymer complex as set forth above" lacks antecedent basis. The identity of one or more locations referenced by the term "above" is not clear.

On p. 14, line 2, the assignment of objects belonging to the abbreviation "PPE" lack antecedent basis.

On p. 16, line 3, the assignment of objects belonging to the abbreviation "DNA-QTL" is indefinite. Correspondence with definitions recited on p. 19, lines 5-8 is not clear. Correspondence with definitions recited on p. 11, lines 12-15 is not clear.

On p. 24, line 15, the assignment of objects belonging to the abbreviation "CRT" lack antecedent basis.

On p. 24, line 14, the object "biotinylated PPE" is indefinite. The synthetic or commercial origin of "biotinylated PPE" is not clear.

On p. 24, line 13, the assignment of objects belonging to the abbreviation "QTL" is indefinite. Correspondence with definitions recited on p. 19, lines 5-8 is not clear. Correspondence with

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definitions recited on p. 11, lines 12-15 is not clear. Correspondence with "BBP" and/or "PPE" is not clear.

On p. 26, line 4, the assignment of objects belonging to the abbreviation "PPE-B" lack antecedent basis.

On p. 27, line 3, the phrase "the above solution sensor" lacks antecedent basis. The identity of one or more locations referenced by the term "above" is not clear.

On p. 27, line 6, the assignment of objects belonging to the abbreviation "RFU" lack antecedent basis.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Samuelson *et al.*, 242 THIN SOLID FILMS 50 (1994).

Samuelson *et al.* describe a sensor for detecting biological recognition events (see Abstract, first sentence, "biosensor") comprising:

a complex comprising:

- (a) a biotinylated fluorescent polymer (see p. 53, left column, first full paragraph, second sentence, "B-PUMT monolayer itself is intrinsically fluorescent");
- (b) a biotin-binding protein (see Fig. 2, "Streptavidin"); and
- (c) a biotinylated phycoerythrin (see Fig. 2, "Randomly Biotinylated Phycoerythrin");

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***Claim Rejections - 35 USC § 112 – first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, claim 31 is amended to recite a sensor comprising three elements: (1) phycoerythrin or phycobilisome, (2) a biotinylated fluorescent polymer, and (3) a biotin-binding protein.

Examiner is unable to locate in the specification, as originally filed, a sensor comprising the three elements listed *supra*. The sensor comprising the three elements appears to constitute new matter.

Applicants are required to cancel the new matter in response to this office Action.

***Claim Rejections - 35 USC § 112 – second paragraph***

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The object "biotinylated fluorescent polymer" is indefinite. The essential structural cooperative relationships between said object and other claim elements appear omitted from claim 31, such omission amounting to a gap between necessary structural connections. See MPEP § 2172.01. The utility of said object within the context of a "sensor" as recited in the preamble is not clear and does not have antecedent support in the specification.

The object "biotin-binding protein" is indefinite. The essential structural cooperative relationships between said object and other claim elements appear omitted from claim 31, such omission amounting to a gap between necessary structural connections. See MPEP § 2172.01. The utility of said object within the context of a "sensor" as recited in the preamble is not clear and does not have antecedent support in the specification.

The phrase "the fluorescent protein" lacks antecedent basis.

The line separation between "a complex of" and the remaining claim language is indefinite. Whether a list is intended is not clear. The identity of list members is not clear. Insertion of a colon (the punctuation mark) after "a complex of" may obviate this rejection.

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***Response to Arguments***

*Claim Rejections - 35 USC § 112 – second paragraph*

In prior Office Action, claim 31 was rejected under 35 U.S.C. 112, second paragraph, because the phrase “biotin-binding protein” was considered indefinite. Specifically, the structural implications of a hyphen between two nouns (i.e. “biotin” and “binding protein”) was not clear. This rejection is withdrawn, notwithstanding Applicants’ argumentation on this issue.

*Claim Rejections - 35 USC § 102*

In prior Office Action, claim 31 was rejected under 35 U.S.C. 102(b) as being anticipated by Adamczyk *et al.*, 3 ORG. LETT. 1797 (2001).

In response, Applicants amend claim 31 to add, *inter alia*, reference to “phycoerythrin or phycobilisome”.

Applicants’ amendment is sufficient to overcome this rejection. Accordingly, this rejection is withdrawn.

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**Conclusion**


No claims are allowed at this time.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Stryer *et al.* (US 4,859,582) describes a composition of matter (see col. 11, line 15, "reaction mixture") comprising a biotinylated fluorescent polymer (see col. 11, lines 17-18, "[p]hycoerythrin-avidin conjugates"), a biotin-binding protein (see col. 11, lines 19-20, "avidin"), and biotinylated phycoerythrin (see col. 11, line 19), relevant to claim 31.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

  
LONG V. LE *m/24/02*  
SUPERVISORY PATENT EXAMINER  
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David J Venci  
Examiner  
Art Unit 1641